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510(k) Summary per section 807.92(c)

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Name of Device: Fiber Optic Phacofragmentation System

Tradename of Device: Phacoscope_{TM}

Equivalence: The subject device combines predicate phacofragmentation system and fiber optic light guides for transmitting visible light.

Description of Device: Phacofragmentation system containing fiber optic light guides directed through fluid channels, and through infusion sleeve.

Intended Use of Device: Provide illumination at surgical site.

Comparison with predicate devices: Medical grade fiber optic guides consistent with Class II classification devices used for intraocular illumination (Classification number 876-1500; Product Code 78FCW) are combined with a phacofragmentation handpiece. Electrical power and light sources for the fiber optic phacofragmentation handpiece (Class II; Classification number 886.4670; Product Code 86HQC) are identical with those currently used. Construction materials are identical with phacofragmentation handpieces and fiber optic devices that are legally marketed devices currently in use. Colors are identical to those in legally marketed devices currently in use.

Sterilization Method: 1) Autoclave for fiber optic phacofragmentation handpiece incorporating quartz fiber optics, or 2) sterilizers customarily used for fiber optic instruments incorporating quartz or plastic fiber optics.

